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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159
7590 12/27/2006 Squire, Sanders & Dempsey, L.L.P. Suite 300 1 Maritime Plaza San Francisco, CA 94111			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/27/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/750,139	Applicant(s) DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/06/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

DECLARATION UNDER 37 CFR § 1.131

Applicant's declaration filed 11/01/2006 has been fully considered and has now rendered the 102(e) rejection and 103(a) rejection in the last office action filed 08/01/2006 moot because the Hunter et al. reference (US 20050149173 A1) no longer qualifies as prior art due to the disclosure within that the inventors conceived of their invention before November 10th 2003. Therefore all of the prior art rejections (35 USC 102(e) and 103(a)) have been withdrawn. The examiner has also withdrawn the 35 USC 112 second paragraph rejections because the currently amended claims renders the rejections moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by applicants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by applicant in IDS filed 11/06/2006). This new ground of rejection was necessitated both by amendment (new claims 53-58) and by applicants newly disclosed IDS filed 11/06/2006.

Pacetti discloses a coating for reducing the rate release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent. See abstract. The polymers include polyurethanes with a polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid) ect. See [0020]-[0021] and claims 11,16-17. The therapeutic agents included anti proliferative-substances, antibiotics, paclitaxel ect. See [0028]. Regarding the limitation that the implantable device is applied to a solution of PEA and a low surface energy, surface blooming polymer, Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition. See [0023]. Regarding claims 45-52 Pacetti discloses several methods of using the coated stents including treatment of obstructions caused by tumors and for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle tissue cells, thrombosis and restenosis. See [0032].

Pacetti does not disclose the use of PEA in combination with the crystalline polymers (same as low surface energy polymer or low surface energy, surface blooming polymer), to produce a coating containing a therapeutic for a stent.

Roby discloses the preparation of polyesteramides and surgical devices fabricated from them. See abstract and pag 1 lin 1-21. Roby is used mostly for the disclosure within that polyesteramides can be used as a coating for surgical devices and the polyesteramide surgical devices could also incorporate therapeutic agents such as antimicrobial agents. See pag 6 lin 3-pag 8 lin 18. The polyesteramide compositions could also be blended with other absorbable or non-absorbable compositions. Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties. Regarding claims 53-58 it is obvious that since both the coatings described in Pacetti and Roby are used for medical devices for use in the body the coating would be biologically benign and since the combination of the coatings described in the references above are the same as applicants claimed invention it is also obvious that the coatings would have the same properties, including biological properties.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Pacetti disclosed the use of both the same low surface energy polymers and low surface energy, surface blooming polymers for a stent coating containing a

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therapeutic as applicants claims while Roby disclosed that coatings for surgical devices containing PEA and therapeutics was already well known in the art at the time of the invention. The motivation to combine the above documents would be to produce and use a coated stent in which the coating comprised a therapeutic, PEA and a highly crystalline hydrophobic polymer (same as applicants low surface energy polymer). The advantage of such a coating would be that the combination would provide a biologically absorbable coating with desirable mechanical properties from the PEA polymer disclosed in Roby and a controlled release of the therapeutic from the crystalline polymers disclosed in Pacetti. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.



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SUPERVISORY PATENT EXAMINER